

Group II. Claims 1 and 15-22, drawn to an in vitro method of identifying an agent that modulates the association of a transcription regulator disclosed in SEQ ID NO:32 and a transcription factor, class 800, subclass 3; and

Group III. Claims 23-27, drawn to a polynucleotide that comprises a transcription regulator and an expression cassette, class 536, subclass 24.1.

Applicants hereby provisionally elect to prosecute the claims of Group I, claims 1-14, with traverse. However, this Restriction Requirement is rendered moot by the following amendments.

Applicants thank the Examiner for taking the time to talk with applicants' undersigned agent on October 18, 2001. During that conversation, the submission of new claims relating to transgenic mice carrying the disclosed SEQ ID NO:32 transcriptional control sequence operably linked to a reporter gene encoding a light-generating protein were discussed. The Examiner indicated that such claims would be considered and that they would likely be in a separate group relative to the claims for which the restriction requirement had already been issued. The Examiner and applicants' representative discussed the submission of a declaration from the inventors concerning exemplary embodiments of the claimed transgenic mice. Such a declaration is attached hereto. The amendments and declaration are discussed further below.

Accordingly, applicants elect to begin prosecution with new claims 28 and 29, as discussed hereinbelow. **If a problem arises regarding applicants' election of claims 28 and 29, the Examiner is respectfully requested to contact the undersigned at (650) 325-7812 to discuss the problem before the issuance of the next Office action.**

## 2) Amendments

In the claims:

Please cancel claims 1 to 27, without prejudice or disclaimer.

Please add new claims 28 and 29 as follows:

--28. (New) A transgenic mouse or progeny thereof, comprising  
an expression cassette comprising a cis-acting transcription regulator operably  
linked to a reporter sequence encoding a light-generating protein, wherein said cis-acting  
transcription regulator consists of the sequence presented as SEQ ID NO:32.

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29. (New) The transgenic mouse of claim 28, wherein said light-generating  
protein is a luciferase.--

Attached hereto is currently pending claim set.

#### Remarks

Claims 1-27 were pending and have been canceled without prejudice or disclaimer. New claims 28 and 29 have been added. Support for the new claims can be found throughout the original claims and specification as filed, for example at pages 42-46 and page 69, lines 18-23 of the specification. No new matter has been added as a result of these amendments and entry thereof is respectfully requested. Applicants reserve the right to file a continuation or divisional directed to the subject matter of the canceled claims at any time during the pendency of this application.

During the telephone conversation of October 18, 2001, the Examiner indicated that declaratory evidence may be required to show enablement of claims directed to a transgenic mouse. Accordingly, applicants submit herewith a Rule 132 signed by Dr. Zhang which establishes the claims as pending are fully enabled by the specification as filed.

It is well-settled that the enablement requirement is satisfied if the applicant's specification teaches one of skill in the art how to make and use the claimed invention without undue experimentation. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). When determining whether the amount of testing required is "undue", the courts have determined that "time and difficulty of experiments are not determinative if they are merely routine." (see, e.g., *In re Wands*, 8 USPQ2d at 1404, citing *In re Angstadt*, 190